

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-20 and 33-54 were examined and rejected.

By this Amendment, claims 1, 9, 13, 40, 42 and 54 have been amended.

The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim.

Support for the claim amendments is found throughout the specification and the drawings and particularly in paragraphs 0038 and 0039. Accordingly, no new matter is added by these amendments.

Claims 1-20 and 33-54 remain pending in the application.

Applicants respectfully request entry of the amendments herein and reconsideration of the application in view of the amendments and remarks made herein.

Double Patenting Rejections

Claims 1-20, 33-39 and 49-53 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,501,976. For the reasons presented in the previously submitted Amendment mailed October 7, 2003, Applicant respectfully submits that the claims of the cited patent and of the subject application are patentably distinct as the respective claimed devices are structurally distinct from each other. However, in order to move the prosecution of the pending claims forward, Applicant herein submits the accompanying Terminal Disclaimer with respect to U.S. Patent No. 6,501,976. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 1-20 and 33-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Application Serial No. 09/879,146. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/879,146 in order to

move the prosecution of the pending claims forward. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 1-8, 20 and 33-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-57 of U.S. Patent Application Serial No. 09/878,742. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/878,742 in order to move the prosecution of the pending claims forward. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 9-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-39 of U.S. Patent Application Serial No. 09/878,742 in view of Joseph (U.S. Patent No. 5,161,532). For the reasons discussed above, the claims of the subject application are not obvious in view of those of U.S. Patent Application Serial No. 09/878,742 in order to move the prosecution of the pending claims forward. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/878,742. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Rejections Under 35 U.S.C. §102

Claims 1-2, 5-8, 20 and 33-54 were rejected under 35 U.S.C. §102(b) as being anticipated by Gough (U.S. Patent No. 4,671,288).

The present invention as claimed in claims 1-2, 5-8 and 20 provides for a planar electrode positioned substantially transverse to at least one skin piercing member and comprising a hole substantially axially aligned with the channel of the at least one skin-piercing member. Claims 33-39 provide for a system comprising a device according to claim 1. Claims 48-53 provide for a method of using the system of claim 33. Claims 40-47 provide for a method of using at least one micro-needle comprising an open distal end and a channel, and transferring absorbed constituents at the open distal end into a measurement chamber comprising a the conductive material substantially transverse to the at least one micro-needle and having a hole substantially axially aligned with the

micro-needle channel. Claim 54 provides for first and second substantially parallel electrodes wherein the second electrode has pores smaller than those of the first electrode, and at least one hollow micro-needle extending substantially transverse to the first electrodes wherein at least one pore of the first electrode is axially aligned with the micro-needle.

While the Examiner correlates the claim limitations of a skin-piercing member/micro-needle, a measurement/electrochemical cell having a planar electrode/conductive material, and a constituent transfer medium with certain elements of Gough's device, the Examiner does not identify an element of the Gough device which provides for or teaches a hole in an electrode/conductive material which is substantially axially aligned with the channel of the skin-piercing member or micro-needle.

It is incumbent upon an Examiner to show that each and every claim limitation of a rejected claim reads on a device or method disclosed in a reference asserted under 35 U.S.C. §102 (see 35 U.S.C. §132). Accordingly, Applicant respectfully asserts that the Examiner has not made a proper rejection under 35 U.S.C. §102.

Notwithstanding the improper rejection, Applicant respectfully asserts that Gough does not disclose, suggest or teach a device and/or method having all of the limitations of the rejected claims. In particular, certain of the rejected claims require a planar electrode/conductive material transverse to a micro-needle/skin-piercing element. Gough's sensors 16 and 18 are wires which are parallel, not traverse, to the needle. Additionally, certain of the rejected claims require the electrode/conductive material to have a hole there through which is axially aligned with a channel of a micro-needle. Gough's sensors do not have holes through them. Others of the rejected claims require that the device have two porous electrodes. As stated by the Examiner in Office Action, Gough does not disclose porous electrodes. Further, certain of the rejected claims require a micro-needle/skin-piercing element having an open distal end. Gough's needle has a closed distal end.

For at least these reasons, claims 1-2, 5-8, 20 and 33-54 are not anticipated nor made obvious in view of Gough. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

Rejections Under 35 U.S.C. §103

Claims 3 and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gough in view of Nitzan (U.S. Patent No. 5,897,522).

As discussed above with respect to the rejection of claim 1, Gough does not disclose, teach or suggest a device having a planar electrode/conductive material transverse to a micro-needle/skin-piercing element, nor an electrode/conductive material having a hole there through which is axially aligned with a channel of a micro-needle, nor a micro-needle/skin-piercing element having an open distal end. Nitzan fails to make up for the deficiencies of Gough as Nitzan is cited solely for its teaching relating to use of a natural gel matrix. Accordingly, for at least the reasons described above, the combination of Gough and Nitzan fails to render claims 3 and 4 obvious. Applicants respectfully request withdrawal of this rejection and allowance of the claims.

Claims 9-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gough in view of Joseph.

As discussed above with respect to the rejection of claim 1, Gough does not disclose, teach or suggest a device having a planar electrode substantially transverse to a micro-needle or having a hole axially aligned with a channel within the micro-needle. Joseph fails to make up for the deficiencies of Gough as Joseph is cited solely for its teaching relating to use of a porous electrode. Accordingly, for at least these reasons, the combination of Gough and Joseph fails to render claims 9-14 obvious.

As discussed above with respect to the rejection of claim 54 and as stated by the Examiner, Gough does not disclose, teach or suggest a device having two porous electrodes. Joseph is relied on solely for its teaching relating to use of a porous electrode and asserts that it would have been obvious to modify Gough in view of Joseph and use a porous electrode. Applicant respectfully disagrees and asserts that there is no motivation to combine Gough and Joseph. Combining the references as the Examiner suggests provides a device having sensors which are porous. There is absolutely no need for Gough to use porous electrodes let alone porous electrodes which are, in essence, wires. Because the wires have a cross-sectional surface area which are very small relative to the diameter of the needle and run parallel to the needle, there is more than

ample space for biological fluid to freely pass within the needle. Moreover, to place pores or holes within these very thin sensor wires is to substantially reduce their ability to perform their intended function. Again, there is no motivation to combine Gough with the teachings of Joseph because (1) Gough does not have a need for porous electrodes, (2) using porous electrodes in the form of wires as employed in Gough's device is not advantageous to passing fluid through a needle, and (3) using porous electrodes in the form of wires as employed in Gough's device is actually disadvantageous to the proper functioning of the electrodes. Accordingly, for at least the reasons described above, the combination of Gough and Joseph fails to render claims 15-19 obvious.

Applicants respectfully request withdrawal of this rejection and allowance of the claims.

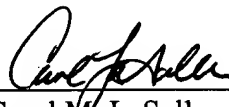
Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-019.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 2/3/04

By: 
Carol M. LaSalle
Registration No. 39,740

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENT\life\019\resp to oa dated 123003.doc